

REMARKS

Claims 17, 20-24, 26-32 and 55-58 are pending in the application. No claims have been added, amended or cancelled in this response. Again, reconsideration of the present application in view of the following remarks, and a notice of allowance on all pending claims are respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 17, 20-24, 26-32 and 55-58 stand rejected as indefinite under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that the Applicant regards as his invention. The Examiner has contended that claim 17 “is ambiguous because of the phrase ‘physical property’. In particular, it is unclear what properties are being examined in the method” (Office Action at 3). The Examiner has requested that Applicant “clarify the phrase in order that one may be able to readily ascertain what is being claimed.” (*id.*).

Applicant respectfully submits that one of ordinary skill in the art would have no difficulty determining the intended meaning and scope of “physical property” as used in claim 17, once placed in possession of the present application. For example, one physical property represented by acquiring an image slice is the concentration of radioactivity within the pulmonary embolus. Applicant’s specification at page 26, lines 3-8 states, with respect to imaging of a thrombus, that “the image slices reflect the concentration of radioactivity within the thrombus. Each image slice is composed of a two-dimensional array of pixels, wherein each pixel comprises an intensity value representative of the concentration of radioactivity at the

particular position within the thrombus which corresponds to the pixel.” Thus, when the present methods are employed, for example, to detect an arterial thrombus, the data acquisition parameters are desirably selected so as to enhance the selectivity for small lesions (see page 26, lines 12-25). In view of these findings, Applicant respectfully submits that one of ordinary skill in the art would have no difficulty determining the intended meaning and scope of the aforementioned claims. Applicant believes that the rejection has been addressed and respectfully requests that the rejection of claims 17, 20-24, 26-32 and 55-58 under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejections under 35 U.S.C. §§ 102(b) or 103(a)**A. Barrett**

Claims 17, 20-24, 26-32, and 55-58 have been rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barrett et al. (Biconjugate Chemistry, 1997, vol. 8, pages 155-160) (“Barrett”). The Office Action states that “both Applicant and Barrett disclose a method of imaging a pulmonary embolic wherein Applicant’s Compound IV is utilized.” (Office Action at 5). The Office Action goes on to contend that Barrett discloses “that the unfiltered images of the complexes in the DVT imaging model as set forth in Figure 6, comprise a scale which represents a fixed scale that increases to the most dense pixel. The region of interest is data acquired from the DVT images comparing the images to the target and the background.” (*id.*).

“It is by now well settled that the burden of establishing a prima facie case of anticipation resides with the Patent & Trademark Office.” *In re Skinner*, 2 U.S.P.Q.2d 1788, 1788-89 (Bd. Pat. App. & Int. 1986). “If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). “Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983). Applicant submits that Barrett does not set forth each and every element of the claimed invention.

Barrett cannot anticipate claims 17, 20-24, 26-32, and 55-58 because the reference does not disclose, explicitly or implicitly, all elements of the claimed invention. In this regard, the pulmonary embolus imaging method of independent claim 17 requires, *inter alia*, localizing a radiolabelled compound at the pulmonary embolus, acquiring image slices representing a physical property of the radiolabelled pulmonary embolus, assembling those slices into a three-dimensional matrix of data, scanning the three-dimensional matrix of data along an array of parallel lines, and assigning the maximum value along each line to a pixel in a two-dimensional array. This method is not disclosed or suggested in Barrett. While Figure 6 of Barrett provides “representative DVT images” of technetium complexes 1-3, there is no suggestion whatsoever that any imaging method was performed that included, *inter alia*, acquiring image slices representing a physical property of the radiolabelled pulmonary embolus, assembling those slices into a three-dimensional matrix of data, scanning the three-dimensional matrix of data along an

array of parallel lines, and assigning the maximum value along each line to a pixel in a two-dimensional array. Accordingly, Barrett cannot anticipate claims 17, 20-24, 26-32, and 55-58.

Barrett also does not render claims 17, 20-24, 26-32, and 55-58 obvious as there is no suggestion or motivation in Barrett to generate Applicant's claimed invention. It is incumbent upon the Examiner, when establishing a prima facie case of obviousness under 35 U.S.C. §103, to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference to arrive at the claimed invention. *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from Applicant's disclosure. *See e.g., Uniroyal Inc. v. Rudkin-Wiley Corp.*, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988); *Ex parte Nesbit*, 25 U.S.P.Q.2d 1817, 1819 (Bd. Pat. App. Int. 1992). But, as stated above, "[i]f the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *Oetiker*, 24 U.S.P.Q.2d at 1444. Applicant submits that the Examiner has not established a prima facie case of obviousness. *See In re Warner*, 154 U.S.P.Q. 173 (C.C.P.A. 1967).

Simply stated, the Examiner has put forth no support for his obviousness determination. The requisite motivation is missing from this reference and it is improper for the Examiner to rely on Applicant's application to find it. There is no suggestion or motivation to modify Barrett to produce Applicant's invention and, as discussed above, the reference alone does not result in Applicant's claimed invention. Accordingly, Applicant's claimed imaging

method that includes, *inter alia*, localizing a radiolabelled compound at the pulmonary embolus, acquiring image slices representing a physical property of the radiolabelled pulmonary embolus, assembling those slices into a three-dimensional matrix of data, scanning the three-dimensional matrix of data along an array of parallel lines, and assigning the maximum value along each line to a pixel in a two-dimensional array, is not rendered obvious by Barrett.

For the foregoing reasons, Applicant submits that Barrett does not anticipate or render obvious claims 17, 20-24, 26-32, and 55-58, and Applicant respectfully requests that this rejection be withdrawn.

B. Sworin

Claims 17, 20-24, 26-32, and 55-58 have been rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,750,088 to Sworin et al. ("Sworin"). The Office Action states that Sworin discloses "the preparation of radiopharmaceuticals useful as imaging agents for the diagnosis of cardiovascular disorders. The imaging agents comprise a stable hydrazone modified biologically active molecule that interacts with gamma emitting radioisotopes to form radiopharmaceuticals that selectively localize at sites of disease and are visualized using gamma scintigraphy." (Office Action at 6).

Applicant respectfully traverses this rejection and submits that Sworin does not expressly set forth each and every element of the claimed invention. Sworin cannot anticipate claims 17, 20-24, 26-32, and 55-58 because the reference does not disclose all elements of the claimed invention. As stated above, the pulmonary embolus imaging method of independent

claim 17 requires, *inter alia*, localizing a radiolabelled compound at the pulmonary embolus, acquiring image slices representing a physical property of the radiolabelled pulmonary embolus, assembling those slices into a three-dimensional matrix of data, scanning the three-dimensional matrix of data along an array of parallel lines, and assigning the maximum value along each line to a pixel in a two-dimensional array. This method is not expressly disclosed in Sworin. Sworin contemplates “a method of imaging the site of thrombotic disease in a patient involving: (1) synthesizing a radiopharmaceutical . . . ; (2) administering said radiopharmaceutical to a patient by injection or infusion; (3) imaging the patient using either planar or SPECT gamma scintigraphy.”

The method of claim 17 is different than standard SPECT techniques (*see, e.g.*, p. 1, lines 21-27, p. 26, lines 1-27) and includes, *inter alia*, taking a two-dimensional image generated by, for example, a technique such as SPECT and assembling those images into a three-dimensional matrix of data that permits localization of the pulmonary embolus (*see, e.g.*, p. 26, lines 28-p.27, lines 33). The claimed method further includes, *inter alia*, acquiring image slices representing a physical property of the radiolabelled pulmonary embolus, assembling those slices into a three-dimensional matrix of data, scanning the three-dimensional matrix of data along an array of parallel lines, and assigning the maximum value along each line to a pixel in a two-dimensional array. Such a method is not taught by Sworin and, accordingly, the reference cannot anticipate claims 17, 20-24, 26-32, and 55-58.

Sworin also does not render claims 17, 20-24, 26-32, and 55-58 obvious as there is no teaching in the reference to generate Applicant’s claimed invention. As with Barrett

discussed above, it is respectfully submitted that the Examiner has put forth no support for his obviousness determination. The requisite motivation is missing and it is improper for the Examiner to rely on Applicant's application to find it. Accordingly, Applicant's claimed method for imaging a pulmonary embolus that includes, *inter alia*, acquiring image slices representing a physical property of the radiolabelled pulmonary embolus, assembling those slices into a three-dimensional matrix of data, scanning the three-dimensional matrix of data along an array of parallel lines, and assigning the maximum value along each line to a pixel in a two-dimensional array, is not rendered obvious by Sworin.

For the foregoing reasons, Applicant submits that Sworin does not anticipate or render obvious claims 17, 20-24, 26-32, and 55-58, and Applicant respectfully requests that this rejection be withdrawn

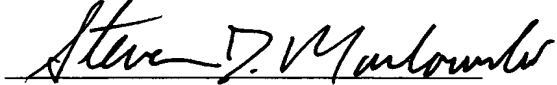
CONCLUSION

Applicant believes that the foregoing constitutes a complete and full response to the Office Action of record. An early and favorable consideration of the present application is respectfully requested.

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